~~43.~~ A composition of matter comprising a spray-dried solid dispersion, which dispersion comprises a sparingly water-soluble drug that is crystalline when undispersed, and HPMCAS, said dispersion exhibiting a maximum supersaturated concentration in MFD solution which is higher by a factor of at least 1.5 relative to the equilibrium concentration exhibited by a control composition comprising an equivalent quantity of undispersed drug.

~~44.~~ A composition as defined in claim ~~43~~, wherein said drug has a dose to aqueous solubility ratio greater than 100.

~~45.~~ A composition comprising a spray dried solid dispersion, which dispersion comprises a sparingly water-soluble drug, said drug being crystalline when undispersed, and HPMCAS, said dispersion effecting, *in vivo*, a maximal observed blood drug concentration (C_{max}) that is higher by a factor of at least 1.25 relative to a control composition comprising an equivalent quantity of undispersed drug.

~~46.~~ A composition as defined in claim ~~45~~, wherein said drug has a dose to aqueous solubility ratio greater than 100.

~~47.~~ A composition comprising a spray dried solid dispersion, which dispersion comprises a sparingly water-soluble drug, said drug being crystalline when undispersed, and HPMCAS, said dispersion effecting, *in vivo*, an area under a curve (AUC) plotting the serum or plasma concentration of drug along the ordinate against time on the abscissa that is higher by a factor of at least 1.25 relative to a control composition comprising an equivalent quantity of undispersed drug.

~~48.~~ A composition as defined in claim ~~47~~, wherein said drug has a dose to aqueous solubility ratio greater than 100.

REMARKS

Cancellations above are made without waiver or prejudice to Applicants' right to file one or more divisionals directed to such cancelled subject matter.

Claims 1-38 were pending in the application. Claims 2, 3, 8, 9, 12, 14, 16, 18, 19, 20, and 21 have been canceled. New claims 39 through 48 have been added.

Applicant has amended the claims in line with the Examiner's suggestions in order to place the application in condition for allowance. None of the amendments discussed below raises any new issues since they, except for the correction of some typographical errors, implement suggestions made by the Examiner in the June 18, 2002 Office Action. Sheets entitled "VERSION MARKED UP TO SHOW CHANGES

MADE" have been appended to this response to indicate the exact nature of the amendments.

Prior to discussing the amendments, Applicants note the following statement by the Examiner in Paragraph 8 on page 5 of the Office Action:

> Claims 2, 3, 6, 8, 9, 12, 14, 16, 18, 22, 28-35 and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The claims, per the above statement, have now been amended in a manner that is in line with the above statement made by the Examiner, and that is accordingly believed to place this application in condition for allowance.

Independent base claims 1, 7, 11, and 15 have been amended to incorporate, respectively, dependent claims 2, 8, 14, and 18, from which support derives, and which have accordingly been canceled. Each of the now-canceled dependent claims specified that the sparingly water-soluble drug has a dose to aqueous solubility ratio greater than 100 mL. It is noted that the above-noted dependent claims were among those the Examiner stated would be allowable if they were rewritten in independent form together with all the limitations of the claim(s) from which they depend. Thus by incorporating claims 2, 8, 14, and 18, respectively, into independent claims 1, 7, 11, and 15, it is respectfully submitted that these independent claims, as now amended, and all remaining claims which depend therefrom, are now allowable.

Although Applicants do not agree with the rejection of claims 19, 20, and 21, these claims have now been cancelled to expedite prosecution.

New Independent claims 39, 43, 45, and 47 have been added. These new claims parallel original (unamended) claims 1, 7, 11, and 15 and, in addition, they now specify that the sparingly water-soluble drug is crystalline. Support is in dependent claims 3, 9, 12, and 16, which have now been cancelled. New claims 39, 43, 45, and 47 thus represent the incorporation of dependent claims 3, 9, 12, and 16, respectively, into original claims 1, 7, 11, and 15. It is noted that the just-mentioned dependent claims were among those the Examiner stated would be allowable if they were rewritten in independent form together with all the limitations of the claim(s) from which they depend. Thus by incorporating claims 3, 9, 12, and 16, respectively, into independent claims 1, 7, 11, and 15, it is respectfully submitted that new claims 39, 43, 45, and 47, and the new claims which depend therefrom, are now allowable. For the sake of completeness, it is noted that all new dependent claims (i.e., new claims 40, 41, 42, 44, 46, and 48) parallel a dependent claim which was already in the application (i.e., claims

2, 5, 6, 8, 14, and 18) and derive their support therefrom.

Claims 28 through 38 have been amended to be dependent from new independent claims 39, 43, 45, and 47.

The term "dose to aqueous solubility" has been amended to be in units of "mL", no unit having been previously specified in the claims. Support derives from the application at page 7, lines 16 to 20, where it is stated that dose is in units of mg and that aqueous solubility is in units of mg/ml. Dividing out the units appropriately, as directed in the specification, yields units of "mL" as the appropriate unit for dose to aqueous solubility.

Claim 7 has been corrected to reflect that the drug is sparingly water-soluble, as stated in all the other independent claims.

Thus Applicants have placed this application in allowance by taking the Examiner's suggestion to incorporate certain dependent claims into the independent claims. The Examiner's suggestion has been fully implemented. No outstanding issues remain for consideration.

In view if the foregoing amendments and comments, it is submitted that this application is in condition for allowance. A Notice of Allowance is accordingly courteously requested.

Respectfully Submitted,

Date: Dec. 16, 2002

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VERSION MARKED UP TO SHOW CHANGES MADE

1. (Twice Amended) A composition comprising a spray dried solid dispersion, which dispersion comprises a sparingly water-soluble drug having a dose to aqueous solubility ratio greater than 100 mL and hydroxypropylmethylcellulose acetate succinate (HPMCAS), said dispersion providing a maximum concentration of said drug in a use environment that is higher by a factor of at least 1.5 relative to a control composition comprising an equivalent quantity of undispersed drug.

Claim 2 has been canceled.

Claim 3 has been canceled.

7. (Twice Amended) A composition of matter comprising a spray-dried solid dispersion, which dispersion comprises a sparingly water-soluble drug having a dose to aqueous solubility ratio greater than 100 mL and HPMCAS, said dispersion exhibiting a maximum supersaturated concentration in MFD solution which is higher by a factor of at least 1.5 relative to the equilibrium concentration exhibited by a control composition comprising an equivalent quantity of undispersed drug.

Claim 8 has been canceled.

Claim 9 has been canceled.

11. (Once Amended) A composition comprising a spray dried solid dispersion, which dispersion comprises a sparingly water-soluble drug having a dose to aqueous solubility ratio greater than 100 mL and HPMCAS, said dispersion effecting, *in vivo*, a maximal observed blood drug concentration (C_{max}) that is higher by a factor of at least 1.25 relative to a control composition comprising an equivalent quantity of undispersed drug.

Claim 12 has been canceled

Claim 14 has been canceled.

15. (Once Amended) A composition comprising a spray dried solid dispersion, which dispersion comprises a sparingly water-soluble drug having a dose to aqueous solubility ratio greater than 100 mL and HPMCAS, said dispersion effecting, *in vivo*, an area under a curve (AUC) plotting the serum or plasma concentration of drug along the ordinate against time on the abscissa that is higher by a factor of at least 1.25 relative to a control composition comprising an equivalent quantity of undispersed drug.

Claim 16 has been canceled.

Claim 18 has been canceled.

Claim 19 has been canceled.

Claim 20 has been canceled.

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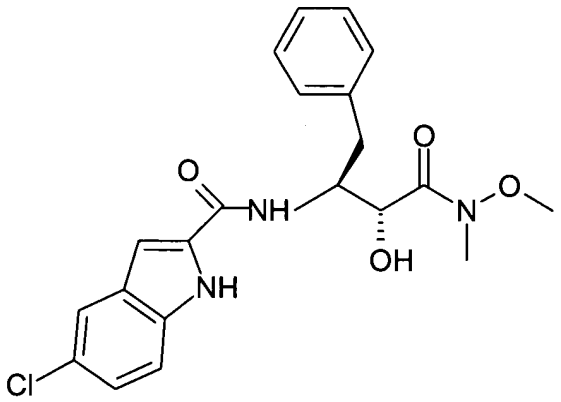
Claim 21 has been canceled.

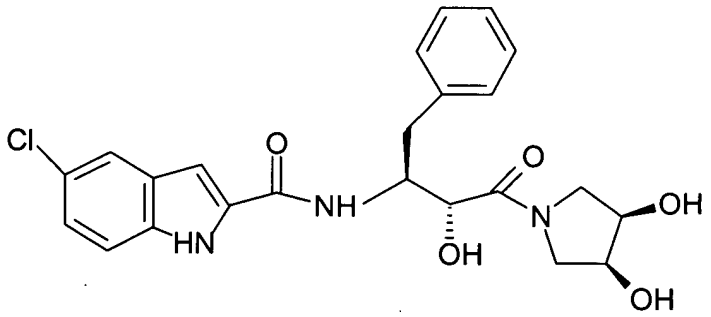
28. (Once Amended) A composition as defined in claims 1, 7, 11, [or] 15, 39, 43, 45, or 47 wherein said drug is a glycogen phosphorylase inhibitor.

29. (Once Amended) A composition as defined in claims 1, 7, 11, [or] 15, 39, 43, 45, or 47 wherein said drug is



or a pharmaceutically acceptable salt thereof.

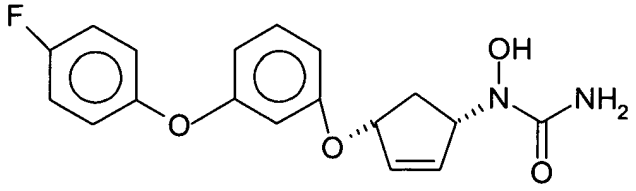
30. (Once Amended) A composition as defined in claims 1, 7, 11, [or] 15, 39, 43, 45, or 47 wherein said drug is



or a pharmaceutically acceptable salt thereof.

31. (Once Amended) A composition as defined in claims 1, 7, 11, [or] 15, 39, 43, 45, or 47 wherein said drug is a 5-lipoxygenase inhibitor.

32. (Once Amended) A composition as defined in claims 1, 7, 11, [or] 15, 39, 43, 45, or 47 wherein said drug is



or a pharmaceutically acceptable salt thereof.

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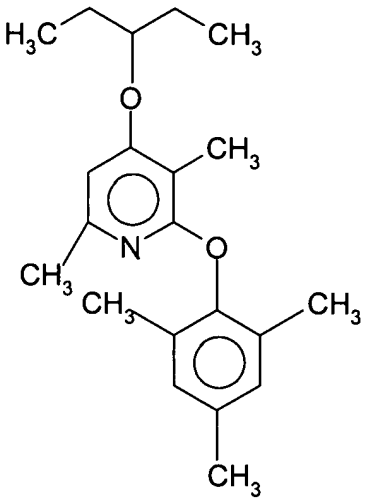
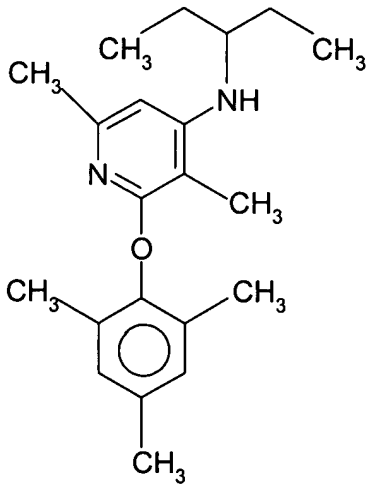
33. (Once Amended) A composition as defined in claims 1, 7, 11, [or] 15, 39, 43, 45, or 47, wherein said drug is a corticotropic releasing hormone (CRH) inhibitor.

34. (Once Amended) A composition as defined in claims 1, 7, 11, [or] 15, 39, 43, 45, or 47, wherein said drug is



or a pharmaceutically acceptable salt thereof.

35. (Once Amended) A composition as defined in claims 1, 7, 11, [or] 15, 39, 43, 45, or 47, wherein said drug is



or a pharmaceutically acceptable salt thereof.

36. (Once Amended) A composition as defined in claims 1, 7, 11, [or] 15, 39, 43, 45, or 47, wherein said drug is an antipsychotic.

37. (Once Amended) A composition as defined in claims 1, 7, 11, [or] 15, 39, 43, 45, or 47 wherein said drug is ziprasidone.

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38. (Once Amended) A composition as defined in claims 1, 7, 11, [or] 15, wherein said drug is selected from griseofulvin, nifedipine, and phenytoin.

The following new claims 39 to 48 have been added.

39. A composition comprising a spray dried solid dispersion, which dispersion comprises a sparingly water-soluble drug that is crystalline when undispersed, and hydroxypropylmethylcellulose acetate succinate (HPMCAS), said dispersion providing a maximum concentration of said drug in a use environment that is higher by a factor of at least 1.5 relative to a control composition comprising an equivalent quantity of undispersed drug.

40. A composition as decribed in claim 39, wherein said drug has a dose to aqueous solubility ratio greater than 100.

41. A composition as defined in claim 39, wherein said use environment is the gastrointestinal tract.

42. A composition as defined in claim 39, wherein said use environment is MFD.

43. A composition of matter comprising a spray-dried solid dispersion, which dispersion comprises a sparingly water-soluble drug that is crystalline when undispersed, and HPMCAS, said dispersion exhibiting a maximum supersaturated concentration in MFD solution which is higher by a factor of at least 1.5 relative to the equilibrium concentration exhibited by a control composition comprising an equivalent quantity of undispersed drug.

46. A composition as defined in claim 43, wherein said drug has a dose to aqueous solubility ratio greater than 100.

47. A composition comprising a spray dried solid dispersion, which dispersion comprises a sparingly water-soluble drug, said drug being crystalline when undispersed, and HPMCAS, said dispersion effecting, *in vivo*, a maximal observed blood drug concentration (C_{max}) that is higher by a factor of at least 1.25 relative to a control composition comprising an equivalent quantity of undispersed drug.

46. A composition as defined in claim 45, wherein said drug has a dose to aqueous solubility ratio greater than 100.

47. A composition comprising a spray dried solid dispersion, which dispersion comprises a sparingly water-soluble drug, said drug being crystalline when undispersed, and HPMCAS, said dispersion effecting, *in vivo*, an area under a curve (AUC) plotting the serum or plasma concentration of drug along the ordinate

against time on the abscissa that is higher by a factor of at least 1.25 relative to a control composition comprising an equivalent quantity of undispersed drug.

48. A composition as defined in claim 47, wherein said drug has a dose to aqueous solubility ratio greater than 100.